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## Boehringer Ingelheim to Commence Phase III Study Investigating the Role of BIBW 2992 (Tovok(TM)) as First-Line Treatment for Non-Small Cell Lung Cancer (NSCLC) Patients With EGFR Mutations

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Ingelheim, Germany (ots/PRNewswire) - - Data From Phase II Studies Investigating BIBW 2992 (Tovok(TM)) and BIBF 1120 (Vargatef(TM)) in NSCLC Patients Presented at 13th World Conference on Lung Cancer (WCLC)

INGELHEIM, Germany, August 3 /PRNewswire/ --

Boehringer Ingelheim announced today at the International Association for the Study of Lung Cancer's 13th World Conference on Lung Cancer (WCLC), San Francisco, CA, the initiation of a Phase III clinical study of BIBW 2992 as first-line treatment in non-small cell lung cancer (NSCLC) patients with epidermal growth factor receptor (EGFR) mutations. BIBW 2992 (planned brand name Tovok(TM)) is the first orally-administered, irreversible dual inhibitor of EGFR and HER2,[1] to reach Phase III development in NSCLC.[2]

This LUX-Lung 3 trial will compare the efficacy and safety of the single-agent BIBW 2992 to that of standard chemotherapy (cisplatin/pemetrexed ) as a potential first-line treatment for NSCLC patients with EGFR mutations.[3] Boehringer Ingelheim's LUX-Lung trial programme currently includes two Phase III trials assessing the efficacy and safety of BIBW 2992 in various NSCLC patient populations across the globe.

"The Boehringer Ingelheim LUX-Lung 3 trial studying BIBW 2992 in patients with EGFR mutations will be important as we continue to work towards providing personalized medicine for patients with lung cancer," said James Yang, MD, PhD, Professor at the Graduate Institute of Clinical Medicine and the Graduate Institute of Clinical Pharmacy at the College of Medicine at the National Taiwan University (NTU). "BIBW 2992 is an irreversible tyrosine kinase inhibitor whose clinical benefit we are hoping to confirm in the first-line setting for patients with EGFR mutations".

This milestone coincides with the oral presentations of new data at WCLC suggesting the compound's potential:

- Preliminary data from the Phase II LUX-Lung 2 trial of NSCLC patients with an EGFR mutation show a response rate of nearly two-thirds (63%) and a disease control rate of 97% in 38 evaluable first-line patients.[4] The most commonly (greater than 5%) observed adverse events were Grade 3 and included diarrhea, skin-related adverse events and mouth ulcerations.[4] Comparable response rates (66%) and disease control (97%) rates were observed in the second-line setting.[4]
- Preliminary data from another study showed that BIBW 2992 improved disease symptoms and reduced the size of tumors in three heavily pre-treated patients with HER2neu mutations.[5] Results from this trial warrant further investigation of BIBW 2992 as a potential new treatment option for NSCLC patients who have HER2neu mutations.[5] On May 29, Boehringer Ingelheim announced that it entered into an agreement with the Manchester, UK-based company DxS to provide a companion diagnostic test kit for BIBW 2992 to identify mutations of the EGFR in patients with non-small cell lung cancer. Under the terms of the agreement, DxS and Boehringer Ingelheim will work jointly to make a suitable companion diagnostic test kit globally available.

Data for BIBF 1120 (Vargatef(TM)) in NSCLC

Also presented at the conference were results from a pharmacokinetic analysis of another Boehringer Ingelheim compound, BIBF 1120 (planned brand name Vargatef(TM)), an angiogenesis inhibitor that simultaneously inhibits vascular endothelial growth factor receptors (VEGFR), platelet-derived growth factor receptors (PDGFR) and fibroblast growth factor receptors (FGFR). The data presented at the conference come from a Phase II study investigating the efficacy and safety of the compound in patients with relapsed advanced NSCLC.6 This double-blind multicenter trial included patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 with relapsed NSCLC after failure of first- or second-line chemotherapy.[6]

The analysis shows that the pharmacokinetics of BIBF 1120 are independent from patient characteristics (e.g., age, weight, height, gender, smoking status, etc.).[6]

Updated efficacy and safety data from this study demonstrate that patients with an ECOG performance status of 0-1 had a median overall survival of 264 days (n=56).[6] These data suggest that BIBF 1120 has single-agent activity in patients suffering from recurrent NSCLC.6 Preliminary data from this study were presented in April 2008 at the 1st European Lung Cancer Conference in Switzerland.

The data presented at WCLC, and the ongoing Phase III development of its two most advanced compounds, mark significant progress for Boehringer Ingelheim's evolving oncology pipeline. In addition to BIBW 2992 and BIBF 1120, Boehringer Ingelheim has several oncology compounds in earlier clinical and pre-clinical development.

Boehringer Ingelheim believes in evidence-based, scientific progress; its extensive oncology clinical trial programme involves more than 800 study centers in 47 countries. Boehringer Ingelheim has a dedicated cancer research center in Vienna where scientists are focused on the discovery and development of new treatments to combat or alleviate the symptoms of cancer.

#### Clinical trial information

Additional information on the LUX-Lung 3 trial will be available on <http://www.clinicaltrials.gov>

The global LUME-Lung Phase III clinical trial programme is investigating BIBF 1120 in combination with standard second-line chemotherapy in patients with advanced NSCLC. The studies are ongoing and with a recruitment target of 2,600 patients worldwide. This is one of the largest Phase III study programs in an advanced NSCLC patient population to date.[7,8]

#### About Lung Cancer

Lung cancer is the world's most common cancer and kills more people than any other cancer. In 2008, approximately 1.52 million new cases of lung cancer were diagnosed worldwide, with 1.31 million people dying from the disease. In the United States, an estimated 161,840 deaths, accounting for 29 percent of all cancer deaths, occurred in 2008, according to the American Cancer Society (ACS).

#### About Boehringer Ingelheim in Oncology

Building on scientific expertise and excellence in the fields of pulmonary and cardiovascular medicine, metabolic disease, neurology, virology and immunology, Boehringer Ingelheim has embarked on a major research programme to develop innovative cancer drugs. Working in close collaboration with the international scientific community and a number of the world's leading cancer centers, Boehringer Ingelheim is committed to discovering and developing novel cancer treatments. This commitment is underpinned by using advances in science to develop a range of targeted therapies in areas of medical need, including various solid tumors and hematological cancers.

The current focus of research includes compounds in three areas: angiogenesis inhibition, signal transduction inhibition and cell-cycle kinase inhibition. BIBW 2992 entered Phase IIb/III clinical development in NSCLC earlier in 2008 and was granted Fast Track designation for a third/fourth line treatment indication in NSCLC by the US Food & Drug Administration. In addition, the LUME-Lung Phase III clinical trial program, which is investigating BIBF 1120 in combination with standard second-line chemotherapy treatments for patients with advanced NSCLC, is ongoing. In the area of cell-cycle kinase inhibition, Boehringer Ingelheim is developing inhibitors of polo-like kinase 1 (Plk1), a protein that is involved in the processes of cell division. These molecules are in the early stages of clinical development.

#### Boehringer Ingelheim

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 138 affiliates in 47 countries and 41,300 employees. Since it was founded in 1885, the independent, family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2008, Boehringer Ingelheim posted net sales of 11.6 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

For more information please visit <http://www.boehringer-ingelheim.com>

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